

CATHETRIX[™] *INNOVATIVE CATHETER SYSTEMS* **FoleySafe**

INSTRUCTIONS FOR USE

CS-000-IFU-REV03

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Indication Of Use:

FoleySafe is a securement device for use with urinary catheters, in which the device is anchored by an adhesive patch to the skin. The FoleySafe is indicated for patients with indwelling urethral catheters, at risk of inadvertent catheter movement and possible extraction. The device can be used by any patient with an indwelling urethral catheter, but it is particularly important for those who are disoriented or have limited body awareness due to long-term catheter use.

General

FoleySafe is a device that keeps catheters securely in place to prevent injuries and inflammation caused by accidental pulling. The FoleySafe cutting mechanism is activated only when the pulling force on the catheter is significant enough and would otherwise result in catheter dislodgement.

Intended Use

The FoleySafe device is used as a securement device which is designed to minimize catheter movement and accidental dislodgement, thereby maximizing comfort.

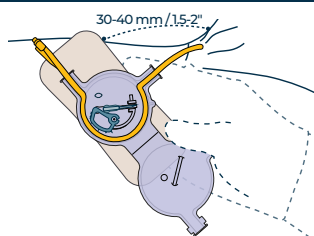
Contraindication:

The FoleySafe device is contraindicated in patients with known tape or adhesive allergies. Evaluate skin integrity before application. The device should not be used with 3-way catheters. Device should not be used in cases in which the catheter length outside the urethra is too short to insert into the device. The device should not be used in catheters with a diameter of less than 12 French or with catheters larger than 16 French. It is safe to use the device for up to 7 days.

Placement Technique:

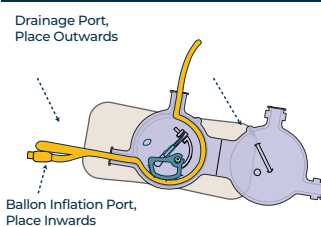
*Always secure catheter into the FoleySafe Stabilization Device retainer BEFORE attaching the adhesive pad on to the skin.

1 Place Catheter Inside the FoleySafe



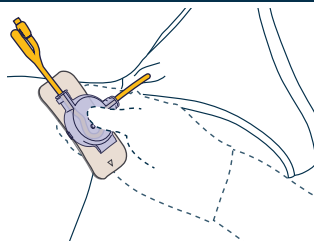
Thread catheter into FoleySafe. The distance between the urethral meatus and the FoleySafe device should be about 30 to 40 mm / 1.5-2" (3 fingers width).

2 Orientation of Foley Catheter Placement



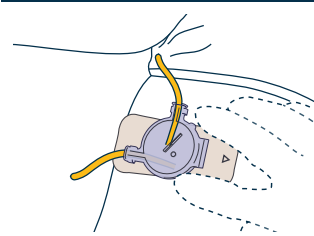
* Important: Make sure Balloon Inflation Port is placed inwards towards the FoleySafe device center.

3 Close FoleySafe



Close lid by placing your fingers under the FoleySafe pad and press the lid with your thumb, being careful to avoid pinching the catheter.

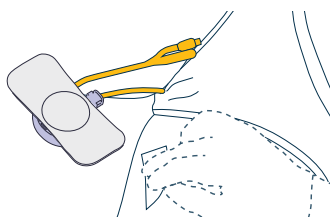
4 Locate a Securement Site



Locate a proper attachment area. Gently lay the FoleySafe securement device straight on the front of the thigh.

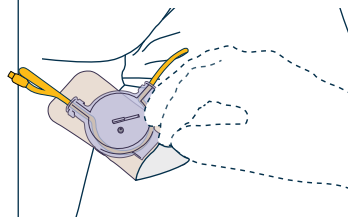
*Make sure leg is fully extended.

5 Shave & Cleanse Securement Site



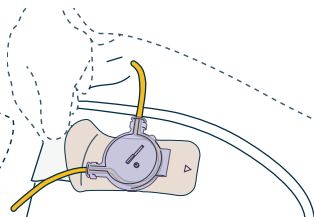
Shave, Clean and degrease securement site with alcohol. Let skin dry. Be sure to clean area larger than securement site.

6 Placement



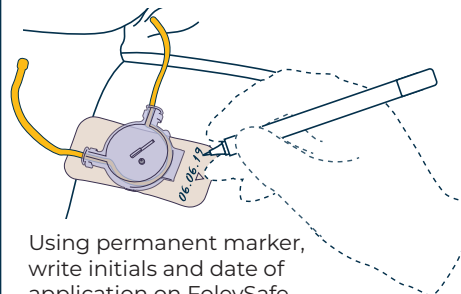
Place the FoleySafe device over the securement site. Be sure to leave 30 to 40 mm / 1.5-2" of catheter slack between meatus and the FoleySafe.
*Make sure leg is fully extended.

7 Peel Paper



While holding the Foleysafe in place peel away paper backing. One side at a time, and place tension-free on skin.

8 Note the With marker



Using permanent marker, write initials and date of application on FoleySafe anchor pad.

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Before Activation:

FoleySafe prevents potential trauma related with accidental pulling on the urethral catheter and/or unintended catheter extraction by utilizing the cutting mechanism.

Activation:

Foleysafe is activated by pulling the catheter between the FoleySafe and the urine collection bag.

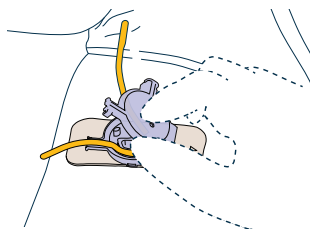
After activation:

- 1 The severed urethral catheter needs to be removed by a caregiver.
- 2 Follow medical instructions to place a new urethral catheter device in case of Foleysafe replacement.
- 3 Dispose of the Foleysafe and place a new one.

*** FoleySafe is a single-use device that can be re-activated only after replaced with a new one.**

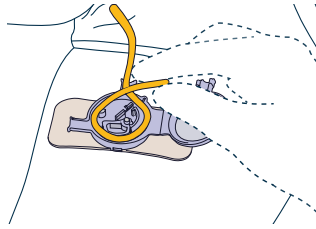
Removal Technique:

1 Disconnecting



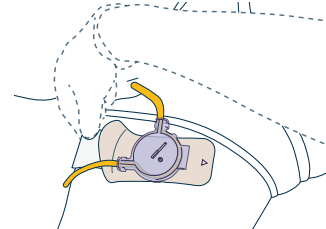
Open FoleySafe lead with its snap latch on its' ends'.

2 Remove Catheter



Gently remove catheter from FoleySafe.

3 Patch Removal



Wipe edge of pad using alcohol pads until a corner lift. Then continue to wipe under surface of pad, in a back-and-forth motion, by squeezing the alcohol out to dissolve adhesive pad away.

***When the sticker has finished its activity, the product may be replaced with a new one without replacing the indwelling catheter. The same catheter remains in place, and a new Foleysafe can be installed.**

Application Instructions

- 1 Evaluate skin integrity before application.
- 2 The FoleySafe securement device should be checked daily.
- 3 If patch becomes soiled wash with soap, water, saline or hydrogen peroxide.
- 4 Do not use alcohol or prepackaged bathing systems, which could lead to early removal of the Foleysafe.
- 5 Consult your healthcare professional about the removal of the FoleySafe stabilization device if you experience any difficulties at removal.


















Disposal Instructions:

Follow local state and federal regulations with respect to environmental protection when disposing of general waste and follow local infectious waste, including all single-use device elements, tools, and material that came in contact with the body or bodily fluids should be incinerated / other general should be segregated & stored in bins marked general. The waste should then be buried in a designated area.

Storage Instructions:

18 months when stored at temperature range of 18-28°C and relative humidity range of 45-55% ,in original package, out of direct sunlight.

Table Of Symbols

	Keep away from sunlight		Consult instructions for use / eIFU Indicator
	Indication of country of origin and manufacturing date: YYYY-MM		CE mark
	Catalogue/reference number		Prescription only
	Manufacturer Lot No.		Manufacturer's name and address
	Medical Device symbol		Authorized representative in the European Community
	Non sterile		Humidity range
	Dry Keep		Temperature range
	Use-by date		Importer
	Single use only		

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